

REMARKS

A Request for a One (1) Month Extension of Time pursuant to 37 CFR§1.136 is attached hereto.

The above-captioned application has been carefully reviewed in light of the Final Office Action to which this Amendment is responsive. Claim 1 has been amended in an effort to further clarify and particularly point out that which is regarded as the present invention and new Claims 21-23 have been added. To that end, it is believed that no new matter has been added. Claims 3, 5 and 15-18 remain withdrawn wherein Applicant retains the right to file divisional applications based on any non-elected subject matter. Therefore, Claims 1, 2, 4, 6-14, 19, 20 and new Claims 21-23 are currently pending in the above-captioned application.

Claim Rejections Under 35 USC §102

1. Claims 1, 2, 4, 6-14, 19 and 20 stand rejected under 35 U.S.C. §102(b) as being anticipated by Regnier et al (U.S. Patent No. 6,156,273, hereinafter referred to as "Regnier").

Applicant respectfully traverses this rejection. In order to successfully advance an anticipation rejection under the Patent Statute, each and every claimed limitation must be found in the single cited prior art reference. Those limitations that are not found in the cited reference must be notoriously well known in the field to one of sufficient (i.e., ordinary) skill in the field.

Regnier relates to an enclosed separation column 10 for use in a separation process such as chromatography, electrochromatography and electrophoresis. The column includes a plurality of support structures 14, as well as a series of interconnected channels. The separation apparatus used herein requires use of a pump for pumping a mobile phase from a reservoir through the separation column; see col. 4, lines 37-41. To that end, a cover plate is further required in order to enclose the system; see Abstract, as well as col. 5, lines 8-23. Therefore any flow path for fluid, even that extending across the microstructures, must be defined, at least in part, by the cover plate.

The present device, on the other hand, does not require a cover plate or a lid in order to adequately create a flow path or a pump or similar apparatus to induce fluidic movement through the device. That is, the present device constitutes an "open" structure in that the at least one flow path consists solely of a plurality of projections, which are spaced and sized in a suitable manner to promote lateral capillary flow and not based upon the action or actuation of a pump or similar external apparatus is not required, nor is a cover plate. Such a plate can be included in the device of the present invention, but this plate does not contribute in any way with the induced capillary action of the device.

The Examiner has opined that "any" zone will meet the criteria for a transport or incubation zone for purposes of interpreting this limitation. Applicant disagrees with this characterization. Nonetheless and even assuming such an interpretation is valid, Regnier still fails to describe a means for controlling capillary flow rate, outside of the pump. The presently claimed device, as now positively stated in amended Claim 1, includes means for controlling fluid flow based on a sink placed at a one end of the device relative to where fluid is first applied (at an opposite end). These means applied to the sink influence fluidic (capillary) flow and more particularly the flow rate of a liquid sample applied to the device. Regnier, on the other hand, fails to provide a sink as defined herein or means for controlling the flow rate over a flow path in which fluid is caused to flow only based on capillary flow.

Claim 1 has been amended in an effort to further clarify the above-noted features and therefore define the open nature of the herein described device for permitting fluid transport. Support is found in the present specification – see, for example, Fig. 1 of the present application as well as paragraphs [0072] – [0077] of the published application. Therefore, it is believed no new matter has been added. Claims 2, 4, 6-14, 19 and 20 are believed to be allowable for the same reasons, since each of these claims depend from amended base Claim 1. Reconsideration is respectfully requested.

2. Claims 1, 2, 4, 6-14, 19 and 20 stand rejected under 35 U.S.C. §102(b) as being anticipated by Bhullar et al. (U.S. Patent No. 6,451,264, hereinafter referred to as "Bhullar").

Applicant respectfully traverses the rejection. As previously noted and in order to successfully advance an anticipation rejection under the Patent Statute, each and every claimed limitation must be found in the single cited prior art reference. Those limitations that are not found in the cited reference must be notoriously well known in the field to one of sufficient (i.e., ordinary) skill in the field.

Bhullar relates to a capillary pathway that includes a plurality of spaced capillary groups spaced about a curved section. As in the case of Regnier above, the entirety of this system is enclosed by a lid 36, see col. 4, lines 38-41. That is to say, the system is not "open" and therefore each of the flow paths must include not only the components of the capillary pathways but an additional cover plate, at a minimum. The at least one flow path of the present invention, on the other hand, consists solely of the plurality of projections – that is, no cover plate is needed for inducing capillary action. As previously noted, Claim 1 has been amended to clarify this distinction. It is believed the Examiner has misinterpreted the intended effect of the term "consists of" for purposes of this claim. Nonetheless, Applicant has further clarified same by indicating the at least one flow path of the present device can be open and still permit fluidic flow via capillary action.

Additionally, this reference fails to describe or suggest means for controlling the fluid flow rate in the device. Various microstructures are shown in varying geometry, each of which independently can create a different flow (velocity) profile for purposes of a curved part of the pathways that are provided, but wherein this profile is otherwise constant or unchanging. That is to say, no means are described for selectively influencing the velocity through these geometries. The present invention, as recited in amended Claim 1, includes means for controlling (i.e., varying) the rate of flow so as to control, for example, the rate of fluid crossing the reaction zone of the device. It is believed Bhullar fails to disclose or otherwise teach these features. Therefore, it is believed Claim 1, as amended, cannot be anticipated by this patent. Claims 2, 4, 6-16, 19 and 20 are believed

allowable for the same reasons as Claim 1 since these claims depend therefrom. Reconsideration is therefore respectfully requested.

3. Claims 1, 6-14, 19 and 20 stand rejected under 35 U.S.C. §102(b) as being anticipated by Ohman et al. (WO 3103835, hereinafter referred to as "Ohman").

Applicant respectfully traverses the rejection. Again and in order to successfully advance an anticipation rejection under the Patent Statute, each and every claimed limitation must be found in the single cited prior art reference. Those limitations that are not found in the cited reference must be notoriously well known in the field to one of sufficient (i.e., ordinary) skill in the field.

It is acknowledged that Ohman describes a micro-fluidic structure, but this reference fails to describe a reaction or incubation zone or any description that relates to fluid movement specifically from a fluid receiving zone through a reaction zone and to a sink disposed oppositely from the fluid receiving zone and reaction zone through which the fluid is caused to move through capillary action.

In addition, it is believed this reference fails to either teach or suggest means for controlling the flow rate across any fluid flow path in the device. While Ohman teaches how capillary action can occur, this reference fails to describe how the flow rate through the microstructure can be controlled. Refer to paragraph [0014] – [0015] of the present application, as published. Claim 1 has been amended in an effort to clarify the above-noted feature and to distinctly describe the invention. Since Ohman fails to disclose essentially claimed matter, it cannot anticipate Claim 1 and therefore Claims 6-14, 19 and 20 are also believed to be patentably distinct. Reconsideration is respectfully requested.

Claim Rejections Under 35 USC § 103

Claims 2 and 4 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ohman. Applicant respectfully traverses this rejection in light of the following discussion.

In order to successfully maintain a "*prima facie*" obviousness rejection under the Patent Statute, each and every claimed limitation must be found in or suggested by the cited art, whether singly or by way of combination. Those limitations that are neither found or suggested by the reference(s) must be notoriously well known to one of sufficient (i.e., ordinary) skill in the field of the invention at the time thereof.

Each of Claims 2 and 4 are dependent upon amended Claim 1, discussed *infra*, in regard to Ohman. As noted, this cited reference describes a micro-fluidic structure but this reference fails to describe a reaction or incubation zone or any description that relates to fluid movement specifically from a fluid receiving zone through a reaction zone and to a sink disposed oppositely from the fluid receiving zone and reaction zone through which the fluid is caused to move through capillary action.

Moreover and as previous noted, this reference fails to teach or suggest any means for controlling the flow rate of a liquid sample across any fluid flow path of the device. While Ohman describes how capillary action can occur in a micro-fluidic structure, this patent fails to teach, describe or otherwise suggest how capillary flow can be suitably controlled in a device, whether an assay device or other. Because Claim 1, as amended, fails to teach or suggest at least one recited feature, there can be no *prima facie* obviousness rejection as to Claims 2 and 4. Reconsideration is respectfully requested.

For the foregoing reasons, it is believed each of Claims 1, 2, 4, 6-14, 19 and 20 are allowable over the art of record. Reconsideration is therefore respectfully requested.

New Claims 21-23 have been added, reciting additional aspects of the herein device as an assay device. Support is found repletely in the specification and drawings for the subject matter of these claims. It is believed no new matter has been added. Entry and favorable consideration is respectfully requested.

CONCLUSION

In summary, it is believed that the presently pending claims in the above-captioned application are now believed to be in immediate condition for allowance. Accordingly, an expedited Notice of Allowability is earnestly solicited.

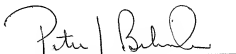
If the Examiner believes a telephone conference would expedite the prosecution of the above-captioned application, the Examiner is invited to telephone Applicant's representative, at the telephone number provided below.

A fee for the Request for One (1) Month Extension, as well as the fee for the Request for Continued Examination (RCE), each accompany this correspondence. It is believed that no other fees are required for the filing of this paper. However and in the event the Office determines that additional fees are required, the Commissioner is hereby authorized to charge the cost of such fees due in connection with the filing of this document or credit any overpayments to Deposit Account No. 50-3010, referencing Docket No. 3032860 US01.

Respectfully submitted,

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